

REMARKS

Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40 and 42 are under examination in the present application. Claims 1, 9, 15-20, 23, 26, 29-36, 38, 40 and 42 stand rejected under 35 U.S.C. §103, as allegedly being obvious over each of Tobias (WO 01/37654) and Mushegian (WO 01/96584) in view of Zipperlin et al. (EMBO J. 20(15):3984-92 (2001)). Applicants note with appreciation the withdrawal of the other previously pending rejections.

Applicants respectfully disagree with the Examiner. The claims are supported by an adequate written description. The Examiner attention is respectfully directed to the Declaration of Dr. Harold Trick (the "Trick Decl."), which rebuts the arguments made by the Examiner in support of the rejection.

The Examiner states that while Tobias and Mushegian teach targeting genes essential for nematode growth/development and parasitism, they do explicitly disclose well characterized embryonic lethal genes from nematodes. The Examiner then states that Zipperlin et al. teaches embryonic lethal genes from *C. elegans*.

In making the obviousness rejection, the Examiner then argues that:

It would have been obvious to one of ordinary skill in the art to use the method of controlling plant parasitic nematodes by transforming the plant with a dsRNA construct that targets endogenous nematode genes essential for nematode development and growth as taught by each of Tobias et al. and Mushegian et al., and to modify that method by incorporating one or more of the embryonic lethal genes taught by Zipperlin et al.; said embryonic lethal genes can be identified and obtained from *Heterodera glycines* using sequence information from cloned *C. elegans* orthologs known in the prior art as suggested by Tobias et al., with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to use dsRNA technology to control *Heterodera glycines* in a transgenic plant, given that the use dsRNA is more safe and effective as compared to other known methods of controlling nematodes in transgenic plants as suggested by each of Tobias et al and Mushegian et al. Therefore, the invention as whole was a prima facie obvious.

Applicants respectfully disagree. There is no basis for the Examiner's statement that, based on the prior art, embryonic lethal genes from *H. glycines* can be used with a reasonable expectation of success. Applicants note that the Examiner has not supported this statement. As stated in the MPEP, §2142:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396

(2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

Here, Applicants respectfully submit that the Examiner has not provided clear reasoning as to why there is a reasonable expectation of success. The Examiner merely states that this is so.

The Examiner's attention is respectfully directed to the Second Declaration of Dr. Harald Trick, which accompanies this response. This Declaration establishes that a person of skill in the art would not believe that the cited references provide a reasonable expectation of success that the claimed invention could be achieved based on the teachings of those three references. In particular, Dr. Trick states that:

The following facts, supported by the literature and my knowledge as a person of skill in the art, establish that a person of skill in the art would not be motivated to combine the references to make plant that express dsRNA specific for *H. glycines* embryonic lethal phenotype genes:

- Urwin et al., *MPMI* 15(8):747-752 (2002)(attached at Tab 1) discloses that dsRNA corresponding to major sperm protein, an embryonic lethal phenotype gene, had no effect on development of *H. glycines*.
- Fairbairn et al., *Planta* 226:1525-33 (2007)(attached at Tab 2) discloses that when nematodes feed on plants that express dsRNA that has been identified as lethal in vitro, the target gene is down-regulated but there is no lethality.
- There is a difference between *C. elegans* and *H. glycines*. *C. elegans* is a free living organism, while *H. glycines* is a parasitic organism.
- None of the references cited by the Examiner teach specific constructs for targeting embryonic lethal phenotype genes in *H. glycines* or constructs that are orally active.
- There is no guidance in the references cited by the Examiner as to what *H. glycines* embryonic lethal phenotype gene constructs should be used or how to express those genes in a plant. At best, there is only a general guidance. Even given the disclosures references by the Examiner, substantial planning and empirical research, as disclosed in the specification of the present application, was required to identify and design constructs for expression of *H. glycines* embryonic lethal phenotype genes in plants.

- A person of skill in the art, with knowledge of the references I provide above as well as the references cited by the Examiner, would recognize that it was not predictable that a dsRNA that is lethal to *C. elegans* would be lethal to a different parasitic organism such as *H. glycines* when expressed in a plant.

Dr. Trick has provided a scientific analysis, based on facts, of why there is no reasonable expectation of success based on the three cited references.

Applicants further note that in *In re Kubin*, the Federal Circuit, in addressing reasonable expectation of success and what is obvious to try, found that it was impossible to find obviousness if:

what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

In re Kubin, 561 F.3d 1351 at 1359 (Fed. Cir. 2009)(citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed.Cir.1988)). The Federal Circuit pointed out that “KSR affirmed the logical inverse of this statement by stating that § 103 bars patentability unless “the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 1359-60.

In the present case, Applicants respectfully point out that the prior art does not provide an established function for dsRNA constructs that are orally active and lethal to *H. glycines* feeding on a plant as claimed. The facts provided by Dr. Trick confirms this and provides facts that establish there was no reasonable expectation of success based on the references cited by the Examiner. In any event, these facts establish that the invention was more than the predictable use of prior art elements according to their established functions.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Each rejection of the Office Action mailed November 12, 2008 has been addressed. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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